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CARDIAC ASSIST DEVICES: COGNITIVE AND BEHAVIORAL FACTORS AMONG PATIENTS AWAITING CARDIAC TRANSPLANTATION

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ABSTRACT

Cognitive functioning and quality of life are salient factors in predicting mortality and morbidity in end-stage heart failure patients receiving cardiac assist devices while awaiting cardiac transplantation. This study focused on cognitive functioning and self-reported quality of life, neurological impairment, and depressive symptoms. Of 103 candidates for cardiac assist devices (HeartMate ThermoCardiosystems, Inc. [TCI] Left Ventricular Devices [LVAD] or Abiomed Biventricular Assist System [Abiomed]) as a bridge to cardiac transplantation at Hahnemann University Hospital, a total of 53 patients completed neuropsychological evaluations. Cognitive factors included visual-spatial and verbal memories, motor speed, grip strength, and cognitive processing speed. In addition, a total of 298 end-stage heart failure (ESHF) inpatients completed the same cognitive measures over the past decade. Overall, cognitive functioning for both groups was within the normal range. Not surprisingly, a series of t-tests revealed that ESHF inpatients performed better than MCAD candidates on most cognitive measures. However, MCAD candidates performed better than ESHF inpatients on the Mental Status Exam, Visual Reproduction Immediate subtest of the Wechsler Memory Scale, and grip strength task with the nondominant hand.

A total of 23 cardiac assist device candidates completed self-report measures of general and disease-specific quality of life, depressive symptoms, memory, and self-reported neuropsychological symptoms. Results did not support the hypothesis that depression would mediate the relationship between cognitive functioning and quality of life. There were significant differences in quality of life between the three groups: ESHF, MCAD, and OHT warranting a discussion of the implications of various definitions of

quality of life. There were no significant gender differences. Major behavioral findings were 1) these patients are resilient in comparison to the general population; their cognitive functioning was not impaired and they were not depressed and 2) there was a strong relationship between self-report depressive symptoms and self-reported neurological impairment.

Key Word List: CARDIAC ASSIST DEVICES, QUALITY OF LIFE, BEHAVIORAL & COGNITIVE FACTORS

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DEDICATION

For my family.

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CHAPTER 1

INTRODUCTION

The current study investigates quality of life and cognitive functioning in patients with cardiac assist devices awaiting cardiac transplantation. Quality of life is variously defined in the literature making it difficult to compare studies and draw conclusions. Furthermore, there is little research on quality of life and cardiac assist devices. Depression and cardiovascular disease are interrelated thereby interacting etiologically and phenomenologically. Cardiac transplantation is associated with improvements in cognitive functioning. However, the impact of cardiac assist devices on cognitive functioning is unknown. As cardiac assist devices improve hemodynamics such as cardiac output and ejection fraction, they are expected to improve cognitive functioning and increase quality of life for end-stage heart failure patients.

The methodology of this study included administration of disease-specific and general quality of life questionnaires, depressive symptoms, memory, and self-reported neurological symptoms. Questions were phrased to assess patients at three time periods: when first diagnosed with heart failure, with cardiac assist device, and following cardiac transplantation. Additional cognitive evaluations included administration of neuropsychological measures assessing memory, motor speed, and cognitive processing speed both pre-device and post-transplant.

Background

Cardiovascular disease is the leading cause of mortality in the United States; nearly 500,000 people die annually (DeLunas & Potempa, 1999; Shapiro, 1996) and it accounts for one third of all global deaths (World Health Organization, 2000). By 2010, cardiovascular disease is expected to be the leading cause of death worldwide (Word Health Organization, 2000). Coronary Heart Disease (CHD) affects more than 11 million people in the United States. Heart failure is a major public health problem in the United States. It has a prevalence of 4 million, incidence of 400,000, and annual treatment costs of $10 billion (Moskowitz, Weinberg, Oz, & Williams, 1997). Cardiovascular disease costs the United States over $117 billion per year and end stage heart failure is a major source of disability and loss or productivity (Shapiro, 1996). According to the American Heart Association, the economic cost of cardiovascular disease was $298.2 billion in 2000, including direct costs and indirect costs that include loss of productivity resulting from morbidity and mortality.

Congestive Heart Failure

Congestive heart failure occurs when the heart is unable to pump enough blood to meet the body's tissue's needs. When the heart fails, it is unable to pump out all of the blood that enters its chambers. Ejection fraction refers to the percentage of blood pumped out during each heartbeat. The New York Heart Association (NYHA) classification system of heart failure includes four classes, ranging from symptoms present with ordinary physical activity to symptoms present at rest. With class IV, ejection fraction less than 20%, the patient experiences severe to complete limitation of activity, and symptoms occur with any physical exertion and even at rest.

Congestive heart failure affects 1% of adults (4,700,000 people according to the American Heart Association) in the United States, is diagnosed in 400,000 Americans annually, accounts for 250,000 deaths annually, and is the primary diagnosis for 900,000 hospitalizations annually (Goldstein, Oz, & Rose, 1998). In adults over the age of 35, one third of all deaths are due to coronary artery disease and the prevalence of congestive heart failure is increasing with the aging population (Shapiro, 1996). Epidemiological studies indicate that over three million patients suffer from congestive heart failure: 30% with Class III or IV congestive heart failure (see Miller et al., 1995). According to Thompson and Shaprio (1994), the major etiologies Class IV CHF are 50% idiopathic, 40% ischemic, and 10% valvular or other miscellaneous.

Treatment

Treatment alternatives for congestive heart failure include coronary artery bypass surgery, dynamic cardiomyoplasty, partial left ventriculectomy (Dimento, 1998), implantation of cardiac assist devices, and cardiac transplantation. Medication and invasive therapies such as coronary bypass grafting, cardiac assist device implantation, and cardiac transplantation relieve physical symptoms of heart disease. Standard medical treatment for transplant candidates includes digoxin, diuretics, ACE inhibitors, vasocilators, beta blockers, and inotropic agents (Miller et al., 1995). However, pharmacological treatment for New York Classification class IV end stage heart failure (ejection fraction < 20%) is only moderately successful. Quality of life outcomes are much more complex and less well understood (DeLunas & Potempa, 1999). While many factors influence quality of life, it is difficult to determine the precise impact of pharmacological or surgical interventions on quality of life.

Cardiac Transplantation. Cardiac transplantation affords prolonged survival (Heshberger, 1997) and hopefully increased quality of life for patients dependent upon inotropes or cardiac assist devices. Transplants became popular during the 1960's although in the 1970's they lost their popularity in the 1970's due to high mortality rates (Nussbaum & Goldstein, 1992). Orthotopic heart transplantation is now a routine clinical operation (Kugler, Tenderich, Stahlhut, et al., 1994). There were 2,290 transplants in 1997; 2,340 transplants in 1998 (National Institute of Health, 2000); and 2,184 in 1999 (American Heart Association, 2000). Survival rates for cardiac transplantation range form 70 to 80% at one year and five years (see Table 1 for a review of survival statistics).

The demand for transplant hearts is much greater than the supply. On an annual basis, between 20,000 and 40,000 Americans would benefit from cardiac transplantation (National Institute of Health, 2000); the number of donor hearts available annually is only 2,000. Many patients die while awaiting cardiac transplantation. Patients on mechanical assist devices and patients in the intensive care unit requiring Inotropic medications share top priority for donor organs (Gil, 1989). Transplant candidates receiving pharmacological treatment have a 10% inpatient survival rate and a 65% 5-year survival rate. Complications of long-term immunosupression, allograft coronary artery disease, and the shortage of donor organs contribute to this success rate. Despite many efforts and the development of new inotropes for medical management, the two-year survival rate is only 50% (Shapiro, 1996).

Cardiac Assist Devices. Mechanical Circulatory Support (MCS) is another therapy for severe end-stage heart disease," (Frazier, 2002, p. 178). Due to the limited donor pool for cardiac transplantation, MCS offers an alternative and bridge to

transplantation (DeRose, Umana, Argenziano, et al., 1997; McCarthy et al., 1998; Morrone, Buck, Catanese, et al., 1996) and prevention of permanent organ damage during the waiting period for transplantation (Abou-Awdi & Frazier, 1992). Mechanical circulatory support devices are indicated following acute myocardial infarction, during post cardiac-surgical cardiogenic shock, and as a bridge to cardiac transplantation (McGinley, Matthews, & Graham, 1990). Cardiac assist devices can be classified as bridges to recovery, bridges to transplant, or alternatives to transplantation (Table 2). Many patients receive implantable LVADS for home use, resulting in continuation and improvement in their quality of life (Shapiro, 1992).

In a recent comparison of LVAD and Inotropic treatment, Aaronson, Eppinger, Dyke, Wright, and Pagani (2002) found that the overall survival rate for the LVAD group (80 at one year and 77 at three and four years) was significantly better than for the Inotrope group (56 at one year and 44 at three and four years). Furthermore, "the LVAD may end up being a permanent implant or destination therapy because the patient and physician have decided that the LVAD is safer than the morbidity an d mortality of immunosupression and transplantation," (McCarthy, 2002, p. 1256). In the year 2010, 70,000 patients annually are expected to be candidates for cardiac assist device (Petrucci, Kushon, Inkles, Fizpatrick, Twomey, & Samuels, 1999). Psychiatric and neurobehavioral factors are important considerations in relation to the cardiac assist devices (Petrucci et al., 1999).

Three types of cardiac assist devices: TCI, Abiomed, and Novacor were implanted at Hahnemann University Hospital in the past in the past decade with varying survival rates (53.3% for the TCI's and 42.8% for the other devices). The TCI LVAD

supports left ventricular function, thereby providing a bridge to transplant (Radovancevic, Frazier, & Duncan, 1992). The Novacor Left Ventricular Assist System (LVAS) is an electronically driven device, which provides left ventricular support as bridge to transplant (Samuels, Kaufman, Morris, Brozena, Twomey, & Brockman, 1997). The Abiomed Biventricular System (BVS) 5000 provides both left and right ventricular support; for patients following postcardiotomy shock (e.g., to wean patients from cardiopulmonary bypass or any irreversible cardiac situation such as viral myocarditis, myocardial infarction, intractable arrhythmia (Samuels, Kaufman, Thomas, Holmes, Brockman, & Wechsler, 1999; Samuels, Holmes, Thomas, Entwistle, Morris, Narula, & Wechsler, 2001).

Hemodynamics

Hemodynamics are of important consideration in relation to neurologic and neuropsychological outcomes of cardiac assist device implantation and cardiac transplantation. Hemodynamics include pulmonary arterial pressure (PAP), right atrial pressure (RAP), cardiac output (CO), right ventricle ejection fraction (EF), left atrial pressure (LAP), pulmonary vascular resistance (PVR), pulmonary vascular resistance index (PVRT), and cardiac index. Prediction of RV failure is important for patient selection; preoperative PAP and low RV SWI were significant risk factors for RV failure and subsequent RVAD use (Fukamachi, McCarthy, Smedira, Vargo, Starling, & Young, 1999). Right atrial pressure, mediated by hydration, measures right ventricular function, whereas left ventricular ejection fraction and pulmonary artery wedge pressure measure overall systolic performance of the left ventricle (Bornstein, Starling, Myerowitz, &

Haas, 1995). Hemodynamics are commonly used in assessing outcomes in studies of the impact of CT on cognitive functioning and quality of life variables.

Quality of Life

Historically, the primary goal of surgery has been prolonging life with little emphasis on quality of life (Walter, Mohan, & Dahan-Mizrahl, 1992). For example, with coronary bypass grafting is a readily accepted lifesaving procedure, with less emphasis on life enhancement (Radley, 1992). Survival is only one goal of successful cardiac transplantation; obtaining quality of life (long-term psychological adaptation into the post-transplant years) is also critical (Dew et al., 1994). Emphasis on quality of life with cardiac transplantation is increasing (McGee & Horgan, 1996). Open-heart surgery greatly impacts the body's physiology and subsequent quality of life. (Walter et al., 1992). Transplant recipients typically worry about insufficient exercise, weight gain, overexertion, biopsy results, dying, negative mood, and negative body image (McGee & Horgan, 1996).

CHAPTER 2

LITERATURE REVIEW

Quality of Life

Consideration of quality of life rather than the simple consideration of length of life is becoming increasing salient and popular in medical care (Wenger, 1992). Quality of life is of particularly essential consideration with respect to medical illnesses when considering therapeutic goals of alleviation of symptoms, improvement of functioning, limitations of the disease, and ameliorating possible psychological consequences. Many life threatening illnesses cause decline in quality of life and some treatments may cause even further deterioration of quality of life (Wenger, 1992).

Defining Health-Related Quality of Life (HRQL)

HRQL is a multidimensional concept and difficult to define. Albert (1998) argues that quality of life is not clearly definable due to cultural differences between patients. HRQL includes physical function, psychological state, social interaction, somatic state (Woodend, Nair, & Tang, 1998) and emotional and cognitive (Schumaker & Cazjkowski, 1993). Specific diseases impact quality of life. For example, cardiovascular disease and treatments affect patients in different ways. Assessment of quality of life is an important factor in determining treatment and health care (Woodend et al., 1998). Treatments may even cause symptoms that adversely affect an individual's quality of life (Shumaker & Cazjkowski, 1993). However, in the case of end stage heart failure patients, tolerating the impact of cardiac assist devices, Inotropes, or transplantation is the only alternative to

prolong life. "Critical assessments of their value [treatment options], as weighed against loss in life quality, are needed," (Shumaker & Cazjkowski, 1993, p. 150).

Stewart-Amidei (1995) defined quality of life as a multidimensional construct including coping, life satisfaction, emotional well being, material life, meaning in life, physical well-being, and social networks. Furthermore, neurocognitive outcomes may affect quality of life and its assessment. For example, neurologic, cognitive, and behavioral deficits make it more difficult to measure quality of life (Stewart-Amideri). Hume (1989) offers a simple definition of quality of life; "an individual's perceived ability to function normally within society," (p. 403). Quality of life includes social functioning, cognitive functioning, emotional functioning, and overall health status (Hume, 1989). Social functioning includes activities with family, friends, and in the workplace. Cognitive functioning includes abstract reasoning, memory, judgment, and alertness. Emotional functioning refers to mood changes and "sick role" behaviors. Economic status and patient's perceptions about their general health status are other important components of quality of life (Hume, 1989).

Intellectual functioning. Walter, Mohan, and Dahan-Mizrahl (1992) found that patients experienced deficits in short-term memory, motor skills, and arithmetic due to cerebral hypoperfusion resulting from low cardiac output prior to cardiac transplantation. Immediately following transplantation, one fifth of patients suffered from delirium, orientation, and mania due to structural cerebral complication and side effects of medications such as steroids and other immunosuppressive agents. However, cognitive impairment typically improved following recovery.

Emotional state. Psychological reactions to cardiac transplantation include fear, anger, depression, and superstitious thinking (Walter, Mohan, & Dahan-Mizrahl, 1992), mood disturbance, disturbance of body image, increased marital and family stress, noncompliance, and organic brain syndromes (Shapiro, 1990). Cardiac transplantation is most likely a last resort with an otherwise fatal alternative (Walter et al., 1992). Delirium is particularly common immediately following the procedure with rates ranging from 4% to 18% (Shapiro). Mood disturbance and mood lability are commonly related to the large doses of steroids immediately post-transplant (Shapiro, 1990).

Occupational Functioning. The goal of cardiac transplantation is long-term quality in mental and physical health, interpersonal relationships, physical and recreational activity, and employment. Occupational functioning is of particular concern due to economic consequences. Inability to return to work for heart transplant recipients and inadequate medical insurance coverage contribute to financial burden (Shapiro, 1992). "Given the high cost of the transplantation procedure, return to work is a highly-desirable goal," (Kavanagh, 1992, p. 413).

Mai and McKenzie (1992) reported that 75% to 95% of patients return to normal pretransplant physical activity and 50% return to full time employment. Reasons for failure to return to work include age, pre-transplant employment, type of work, and availability of disability payments (Kavanagh, 1992) and steroids. In a survey of cardiac transplant patients, 69% who did not receive LVAD support were unable to return to work within one year of transplantation, whereas 92% of patients receiving LVAD support were able to return to work or capable of doing so (Abou-Awdi & Frazier, 1992). Kavanagh (1992) reported that 82% (under the age of 45), 76% (between 46 and 55), and

10% (over the age of 55 years) of patients who were working 6 months prior to transplant returned to work. Cardiac rehabilitation also increased likelihood of returning to work.

In a study of 25 heart transplant recipients at 7 transplant centers, 45% were employed, 36% unemployed, 13% medically disabled, and 6% retired (Paris, Woodbury, Thompson, Levick, Nothegger, Hukins-Slade, Arbuckles, & Cooper, 1992). Of those employed, 87% returned to their previous employment following transplant and 13% found new employment. Of those unemployed, 16% were working on job applications, whereas 63% had no current plans to seek employment. Paris and colleagues (1992) concluded that length of disability prior to transplant, patients' self-perception of being physically unable to work, and potential loss of health insurance or disability negatively influenced patients' return to work. On the contrary, patients whose health insurance policy did not accept their disability claims were more likely to seek and find employment (Paris et al., 1992).

Social Functioning. Social functioning refers to performing of social roles. Patient's ability to relate to their family members and friends is an important aspect of recovery from cardiac transplant (Abou-Awdi & Frazier, 1992). Cardiac transplantation often leads to role strain and adjustment (Shapiro, 1992). Thus, patients and their family members often benefit from individual and family therapy to facilitate adjustment. "Patients who have a goal to live for, such as those wishing to return to work or spend more time at home have been shown to be better surgical candidates," (Walter, Mohan, & Dahan-Mizrahl, 1992, p. 82). "About 75-95% return to normal activities but only 50% return to previous employment, because of attitude problems . . . 80% returned to full or

part-time work compared with the 4.9% of patients working before the operation," (Walter et al., 1992, p. 83).

Coping ability greatly impacts psychosocial adjustment and quality of life following cardiac transplantation (Shapiro, 1992). When a member of a couple undergoes cardiac transplantation, coping with heart transplantation involves two individuals (Grundbock, Bunzel, & Schubert, 1992). During the waiting period for a donor heart, changes in family interaction and role assignment typically occur. During the postoperative period, the couple restructures their lifestyle based on the transplant recipient's unpredictable future.

Body Image. Body image disturbance typically occurs in 25% to 50% of heart transplant recipients (Shapiro, 1990) and is of particular concern for women and children (Shapiro, 1992). Heart transplantation often changes patients' perceptions of themselves and causes them distress about their physical appearance, particularly due to the side effects of steroids.

Physical Functioning. Physical functioning is another facet of quality of life referring specifically to a patient's physical abilities and limitations and subsequent impact on quality of life. Ades, Maloney, Savage, and Carhart (1999) reported that physical function in coronary patients correlated with age, gender, and mood state. Older age, female gender, low exercise capacity and strength, and higher depression predicted poorer physical functioning. In a study of functional health outcomes in sudden cardiac death survivors, Sauve (1995) found that few sudden cardiac death survivors experienced psychological distress, despite decreases in physical functioning and cognitive impairments.

Compliance. Compliance with the prescribed medical regimen following cardiac transplantation is essential to continue life. Furthermore, noncompliance is associated with poor quality of life and increased morbidity and mortality (Shapiro, 1992). Poor compliance with the medical regimen ranges from 23% to 39% (Shapiro, 1990). Young age, decreased family support, and geographical distance from the transplant center are associated with noncompliance. Brennan, Davis, Buchhotz, and Kuhn (1987) found that personality disorders predicted poor quality of life following cardiac transplantation, specifically noncompliance with the medical regimen.

Measuring Health-Related Quality of Life

The impact of an illness or intervention on a patient's quality of life is a necessary and important aspect of medical research (Dempster & Donnelly, 2000) and evaluation of health care programs (Lalonde, Clarke, Joseph, Mackenzie, & Grover, 1999). Quality of life assessment is widely accepted and further understood as a multidimensional concept including physical, psychological, and social functioning (de Boer, Spruijt, Sprangers, & de Haes, 1998). However, the structure of quality of life is poorly understood. de Boer and colleagues (1998) suggest that disease-specific quality of life can be considered one construct for different disease.

There are various views on quality of life assessment (e.g., Steven, 1998; Frank et al., 1998) although most researchers agree that the patient's self-assessment is an important part of evaluation and treatment planning. Quality of life measurement development requires validity, and reliability (Cohen, 1999). Woodend, Nair, and Tang (1998) further recommend that quality of life measures are self-administered, relatively short (less than 60 minutes to administer), and simple to read and score.

There is currently no gold standard for measuring quality of life (Hume, 1989). Dijkers (1999) distinguished between objective and subjective approaches to quality of life assessment. Objective approaches emphasize common perception of quality of life, whereas subjective approaches emphasize individual cognition and life satisfaction and focus on affect. In quality of life assessment, Guyatt (1994) recommends the following principles when using questionnaires: recognition of importance, training interviewers, and monitoring. Of particular importance is recognizing the need for assessing health related quality of life for all members of transplant teams including surgeons, cardiologists, nurses, psychologists, neuropsychologists, and clinical social workers. Subsequently, training and monitoring of quality of assessment must include follow-up evaluation.

Health-Related Quality of Life Measures

Health-related quality of life measures are either generic (pertaining broadly to quality of life) or disease-specific (pertaining to specific aspects of a disease). Dempster and Donnelly (2000) found that the Medical Outcomes Study Short Form-36 (SF-36) was strongest psychometrically general measure of health-related quality of life when compared to other measures such as the Nottingham Health Profile and the Sickness Impact Profile. Brown and colleagues (2000) also found the SF-36 to be a more sensitive measure of health related quality of life than the Nottingham Health Profile in a study of survivors of myocardial infarction. In terms of disease-specific measures of quality of life, Dempster and Donnelly (2000) support use of the Quality of Life after Myocardial Infarction questionnaire for heart failure classes I – III. The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a valid and reliable measure of disease-

specific quality of life for patients with congestive heart failure (Green, Porter, Bresnahan, & Spertus, 2000). The KCCQ is more sensitive than the Minnesota Living with Heart Failure Questionnaire and the SF-36 (Green et al., 2000).

Quality of Life Research

In a recent study of quality of life and cognitive status, Dew and colleagues (2001) found that patients with ventricular assist devices had poorer cognitive status and were less likely to return to work than non VAD patients. However, this study did not include a complete neuropsychological evaluation and therefore did not determine precise levels of cognitive impairment. Dew and colleagues (2001) also purported that cognitive impairment leads to reductions in daily functioning and quality of life.

Riedinger, Dracup, and Brecht (2000) conducted a study of predictors of quality of life in women with heart failure. They found that for women (mean age = 61, mean ejection fraction = 27%), higher levels of dyspnea, life stresses, and New York Heart Association class predicted lower levels of quality of life. In addition, smoking and vasodilator medication use were associated with decreased quality of life. Ischemic heart failure was associated with decreased social life dissatisfaction and increasing age was associated with increased general life satisfaction.

In a study of patients with coronary heart disease surviving coronary arrest, Motzer and Stewart (1996) found that social status, perceived social support, self-esteem, and instability of chronic illness trajectory accounted for 50% of the variance in quality of life. In addition, they found that sense of coherence added 15% to the incremental variance in quality of life. They suggested that sense of coherence is a salient factor predicting quality of life in cardiac patients. Motzer and Stewart (1996) defined a sense

of coherence in terms of comprehensibility, manageability, and meaningfulness of life with respect to change. A sense of coherence is typically crystallized by the age of 30, but amenable to change with intervention. In another study, Delunas and Potempa (1999) found that hostility, anxiety, and threat appraisal affect quality of life and outcome following treatment for CHD.

Bunzel, Grundbock, and Wollenek (1992) found that patients exhibited improvement the following dimensions of quality of life: physical, emotional, mental, vocational, sexual status, financial situation, leisure activities, partnership, and overall quality of life. However, patients did not exhibit improvement in financial and status following transplantation. Etiology such as coronary artery disease or cardiomyopathy and age did not account for any variance in quality of life or life satisfaction. Konstam, Surman, Hijjazi, and colleagues (1997) studied 29 patients undergoing cardiac transplantation, assessing quality of life at 5 intervals. They found that patients exhibited significant improvements in quality of life physical scores on the Sickness Impact Profile at four months post-transplant, compared with 5 months pre-transplant.

In a study of patients with dilated cardiomyopathy, Steptoe, Mohabir, Mahon, and McKenna (2000) found that patients had significant impairments in physical functioning, role limitations due to physical and emotional problems, social functioning, mental health, perceptions of general health, sleep, and vitality. Quality of life impairments correlated with low shortening fraction, high left ventricular end diastolic diameter, heart failure, and mitral regurgitation. Patients also had higher levels of anxiety and depression compared with a normal sample. Psychological adjustment was associated with quality of life and psychological well-being.

Quality of Life for Patients Awaiting Cardiac Transplantation. Patients in end-stage heart failure who undergo cardiac transplant evaluation often have one year or less to live, while their physical and psychological conditions progressively decline (Nussbaum & Goldstein, 1992). Health status if the most salient predictor of quality of life: a multidimensional construct with objective and subjective dimensions (Shapiro, 1992; Evans, 1992). Objective indicators include ability to work, employment, functional ability, and health status, whereas subjective indicators include psychosocial and psychological variables such as well-being, life satisfaction, psychological affect, and happiness.

"The success of heart transplant has meant considerable pressure to demonstrate that the enormous costs are justified in benefits for quality of life as well as expectation of life," (Mayou, 1990, p. 105). Research indicates that patients and families "require extra psychological and social support if they are to avoid distressing psychosocial complications and gain maximum benefit," (Mayou, 1990, p. 105). Multiple assessments at multiple times of quality of life in cardiac transplant recipients provide insight into changes in quality of life and allow for meaningful comparisons (Caine, Sharples, & Wallwork, 1992). For example, in patients undergoing cardiac transplantation, better psychological functioning is associated with better sleep patterns, better social functioning, improved vitality, less loneliness, and older age (Littlefield, Abbey, Fiducia, Cardella, Greig, Levy, Maurer, & Winton , 1996). Transplantation is associated with overall improved quality of life despite impairments in physical and social functioning due to difficulty in complying with the medical regimen and the intrusive nature of the course.

Factors contributing to higher stress levels among patients awaiting cardiac transplantation include requiring a heart transplant, having a terminal heart disease, and worrying family members (Porter, Krout, Parks, et al., 1994). Porter and colleagues reported the most common and effective coping strategies: thinking positively, using humor, and trying to keep life as normal as possible. They further suggest that cardiac transplant teams should encourage positive coping strategies in patients and families awaiting transplantation and monitor patients and their family members. Konstam, Surman, Hijjazi, and colleagues (1999) investigated the impact of stress levels of patients and their spouses on quality of life (using the Sickness Impact Profile) both pre- and post-cardiac transplantation. They found that patients' stress levels and spousal stress levels predicted quality of life functioning, accounting for 58% of the variance in the patient at one month pre-transplantation. Patients commonly respond to stress and cardiac illness with psychosocial dependency, the need for emotional protection and social support after a significant health status change, which impedes psychological adjustment (Riegel, Glaser, Thomas, Gocka, & Gillespie, 1997).

Quality of Life and Cardiac Assist Devices. There is insufficient research on quality of life and cardiac assist devices (Moskowitz, Weinberg, Oz, & Williams, 1997; Baldwin, Radovanncevic, Duncan, et al., 1991). In terms of quality of life and cardiac disease, problems with quality of life research include "overemphasis on general concepts, neglect of mental state, failure to recognize the range of individual response, neglect of individual meaning of quality of life, and neglect of consequences for the family," (Mayou, 1990, p. 100). Problems with quality of life measurement include "unrepresentative samples, reliance on ad hoc measures, excessive preoccupation with

standard general measures, neglect of mental state, neglect of other aspects of quality of life of particular importance to patients and families, measures often insensitive to clinically important change, self-report preferred to interview-based measures, and failure to compare with control groups," (Mayou, 1990, p. 100).

Dew, Kormos, Winowich, and colleagues (1999) found that quality of life for LVAS outpatients was better than LVAS inpatients and OHT outpatients on physical, emotional, and social functioning domains. QOL for LVAS outpatients also improved over their own QOL before discharger, particularly in the physical functioning and emotional status domains. In another study of 27 cardiac assist device recipients, 67% experienced major complications including bleeding, serious infection, renal failure, and stroke (Kanter, Rizevich, Pennington, et al., 1988). Of the 23 survivors 74% returned to Class I heart status, 9% Class II, 13% Class III, and 4% Class IV. In terms of quality of life and employment, eight returned to full time employment, three were retired, four attended school, three attended preschool, one was a homemaker, and one was unemployed but free of symptoms. Overall, patients had satisfactory long-term quality of life and survival.

Moskowitz, Weinberg, Oz, and Williams (1997) investigated quality of life for long-term LVAD use as compared to the alternative of medical therapy including quality of life assessments at pre-LAVD implantation, peri-LVAD, and post-transplant. However, their Quality of Life measure consisted of a health ranking (0=dead, 1=full health) and patients' responses to a standard gamble (e.g., "Imagine you are no longer a candidate for cardiac transplantation. You are also told that a new treatment for your heart disease is available (a pill)," (Moskowitz et al., 1997, p. 1769). Patients are

required to make a choice between their current treatment and the possibility of the panacea pill. Limitations of their study include the utility of their quality of life measure and incomplete data collection, which is common for studies of seriously ill patients. Dew, Kormos, Winowich, and colleagues (2000) reported that quality of life during VAD support is equal to or better than quality of life for other transplant candidates without VAD support. Shapiro, Levin, and Oz (1996) suggested that neuropsychiatric factors play a great role in quality of life and outcome for LVADs and cardiac transplantation.

In a most recent study of quality of life and LVAD implantation, Grady, Meyer, Mattea, et al. (2001) found patients were satisfied with their lives, experienced low amounts of stress and functional disability, coped well, and perceived themselves as having good health and quality of life. Two weeks following device implantation, patients reported significantly better quality of life, less symptom distress, greater satisfaction with health and functioning. However, patients reported self-care disability and socioeconomic dissatisfaction following device implantation.

With LVAD support, patients may return to NYHA Class I cardiac status and experience improved functional status such that they may become self-caring and leave the hospital, thereby reducing healthcare costs and improving their morale (Frazier, 1994; Myers, Dasse, Macris, et al., 1994). Dew and colleagues (2000) reported that outpatients with ventricular assist device support were more concerned about device noise and risk of stroke than inpatients, while inpatients were more concerned about infection.

In a retrospective study of 12 VAD survivors, 16% reported that the emotional effects of the device were worse than the physical effects, whereas 50% were unsure (Cleavinger & Smith, 1993). In addition, 83% endorsed that they would recommend a

device to someone who needed it, and 67% would reconsent to using the device again if needed. In conclusion, Cleavinger and Smith (1993) identified the following quality of life issues for the device patient: optimization of patient care, dealing with complications, limitations in mobility, and possible termination of support, and obtaining adequate rest (device noise, physical discomfort, anxiety, and interruptions to check device performance).

Quality of Life in Primary Caregivers. In addition to investigation quality of life with in heart failure patients, it is also important to investigate the quality of life of the primary caregivers. Stressful factors for primary caretakers of transplant recipients include increase in tasks not completed, having a family member seriously ill, and financial strain (Savage & Canody, 1999). The spouse of a transplant candidate plays a key role in determining patient well-being and quality of life, although sometimes at the expense of the psychological and physical well-being of the spouse (Konstam, Surman, Hijjazi, et al., 1997). For example, spousal support is the best predictor of medical compliance for treatment of hypertension. End-stage heart failure affects the quality of life of both the patient and the spouse in interacting, complex, dynamic ways. Specific measures of quality of life in cardiac spouses do exist (e.g., Quality of Life for Cardiac Spouses; Ebbesen, Guyattm, McCartney, & Oldridge, 1990). In a study of QOL and LVAS patients, family caregivers reported increased caregiving burden following patient discharger, but overall well-being was not adversely affected (Dew, Kormos, Winowich, et al., 1999).

Dew, Switzer, DiMartini and colleagues (2000) investigated human factors for ventricular assist device recipients and their family caregivers via interview. They found

that patients' and caregivers' perceptions of health status and well-being did not differ. Patients' concerns included infection, difficulty sleeping due to the location of the driveline exit site, device malfunction, and device noise. All patients reported concerns about physical functional limitations, psychological distress, and reduced quality of life.

Quality of Life After Heart Transplantation. Difficulties for patients following cardiac transplantation include employment, financial burden (e.g., issues around welfare, health insurance, and inability to return to work), and satisfaction with sexual relationships (see Shapiro, 1992 for a review). Most transplant recipients report improved mood and well-being following transplantation. However, steroids may induce psychiatric problems both directly by their effect on the central nervous system) and indirectly by their side effects such as weight gain.

Psychological adjustment for children following transplantation is particularly difficult around issues of body image and effects on their families (Shapiro, 1992). Psychological adjustment is a major contributing factor to quality of life; poor psychological adjustment leads to decreased quality of life and increased physical morbidity (Dew, Kormos, Winowich, et al., 2001). Cognitive functioning is another important factor contributing to quality of life following cardiac transplantation (Schall, Petrucci, Brozena, Cavarocchi, & Jessup, 1989).

Recommendations

Various clinicians and researchers provide recommendations for protocols to measure quality of life and cognitive functioning in these patients. For example, Avis, Czaiowski, Dew, and colleagues (1995) recommended a protocol to measure HRQL for device patients with the following QOL dimensions: cognitive, emotional, social,

physical, sexual/intimacy, productivity, overall well-being, device specific, open ended questions, and TrailMaking, Logical Memory, Digit Symbol, and the Rey Complex Figure at Baseline, 12 months, and 24 months.

Behavioral Factors

Physiologically and metaphorically, the heart is an essential part of our identity and social function (Shapiro, 1996). Psychiatric disorders such as Type A behavior pattern and hostility, anxiety, and depression frequently coexist with cardiovascular disease. Depression is of particular concern for cardiac patients due to the high prevalence and depression and the physiological correlates of depression and cardiovascular disease. The following is a review of psychiatric considerations before and after cardiac transplantation (CT) and predictors of successful CT.

Depression and Cardiovascular Disease

The comorbidity of depression and cardiovascular disease is "an inevitable consequence of the relationship between the two conditions," (Roose, 2001, p. 19). Depression and cardiovascular disease interrelate etiologically and phenomenologcially. Specifically, depressed patients have increased platelet activity, thereby increasing risk for platelet-induced ischemic events. Depressed patients also have heart rate variability from decreased parasympathetic tone. Cardiovascular patients with depression are at increased risk for fatal ischemic heart disease and depressed patients have a high rate of sudden cardiovascular death. Depression affects 20% of myocardial infarction (MI) patients (18% meet criteria for Major Depressive Disorder and 27% experience depressive symptoms) and is associated with reduced quality of life and occupational functioning and increased mortality (Shapiro, 1992). Depression in patients with

coronary artery disease predicts increases in rehospitalization, disability, healthcare cost and decreases in symptom relief following surgery and survival. (Brummett, Babyak, Barefoot, et al., 1998). In addition, depressive symptoms may impact cognitive functioning; in a study of 40 adults, Williams, Little, Scates, and Blockman (1987) found that depressed adults reported more memory problems than nondepressed adults, perhaps due to depressive cognitive distortions such as negative self-evaluation.

Psychiatric Considerations Before Cardiac Transplantation

"Heart transplantation confronts the patient with major physical, psychological, and social demands, both before and after the operation. Psychological adjustment with these stressors requires effective coping abilities," (Zumbrunnen, 1989, p. 66). The heart transplantation process requires multidisciplinary team evaluations (Sears, Rodrigue, Sirious, Urizar, & Perri, 1999) providing initial medical and psychiatric histories and making numerous and complex decisions (Houser, Konstam, & Konstam, 1992). In addition to severe limitations in quality of life and prognosis, the absence of physical of emotional factors, which would hinder survival, determine recommendation for transplantation. Candidates for cardiac transplantation are in end stage heart-failure (Class IV) with ejection fraction less than 20%, are in rapid decline, and may have symptoms of fatigue, insomnia, anorexia, hepatic and pulmonary congestion, and poor exercise tolerance (Levenson & Olbrisch, 1993). For these patients, their prognosis is quite poor without successful transplantation.

Psychiatric contraindications of cardiac transplantation include florid psychosis, alcohol or drug dependence, personality disorder, and poor social support (Zumbrunnen, 1989). Exclusion criteria for cardiac transplantation include serious medical illnesses

(e.g., advanced pulmonary disease or metastatic cancer). Most transplant programs (70%) exclude patients for active schizophrenia, dementia, suicidal ideation, suicide attempts, mental retardation, current alcohol or substance abuse (Levensen & Olbrisch, 1993). However, exclusion for tobacco use, obesity, noncompliance, criminality, personality disorder, mild mental retardation, controlled schizophrenia or affective disorders, and a history of alcohol or substance abuse lead to controversy for transplant programs. Social support is another important factor for determining candidate selection and predicting success (Table 3). Due to the ceiling effect of social support in the cardiac transplant population, as it is required for transplant candidacy, social support was not investigated in the current study.

Psychiatric problems with transplant recipients include bipolar mood disorder due to steroids, major depression, delirium, pain, sexual dysfunction, family adjustment problems, and noncompliance (Shapiro, 1996). Fifty percent of heart transplant candidates have psychiatric disorders such as adjustment disorder and psychological factors such as depression and anxiety affecting their medical condition (Levensen & Olbrisch, 1993). Other psychiatric issues include denial of illness, noncompliance, ambivalence, substance abuse, and cognitive impairment. Common cognitive deficits include neuropsychological deficits resulting from heart disease, MIs, and cardiac surgery, delirium resulting from cyclosporine toxicity, steroid psychosis, or rejection encephalopathy, hypoxia, electrolyte disturbance, renal or hepatic failure, hyperglycemia, acute infection, drug toxicity, and cerebrovascular emboli.

Psychiatric Factors Following Transplantation

Transplant recipients have a high prevalence of adjustment disorders, organic mental syndromes, and other psychiatric problems (Shapiro, 1992). Prevalence rates of major depression and steroid-induced depression range from 10% to 20% and often go undiagnosed and untreated. Difficulties for heart transplant recipients following transplantation include inability to return to work, psychopathology, sleep disturbance, organic brain syndrome, mood-cognitive-perceptual disorder, marital distress, anxiety, depression, and psychosocial adjustment to illness (see Shapiro & Kornfeld, 1989 for a review). Affective disorders are particularly common in patients taking high doses of prednisone following transplantation.

Shapiro and Kornfeld (1989) evaluated the prevalence of psychiatric disorders and psychosocial problems following cardiac transplantation. Fifty-one percent of patients had affective disorders (chiefly steroid-related) including mood lability and irritability, grandiosity (22%), major depressive episodes (11%), and anxiety symptoms (26%). Patients also experienced cognitive, social, and occupational difficulties (Shapiro & Kornfeld, 1989). Magni and Borgherini (1992) reported that of 47 transplant recipients; generalized anxiety disorder (35%) and major depression (19%) were the most frequent psychiatric diagnoses prior to cardiac transplantation. Two patients developed post-transplant delirium. Psychological distress (i.e., depression, anxiety, psychoticism, and interpersonal sensitivity) improved following transplantation.

Family difficulties following transplantation include spousal anxiety, depression, and anger, acting out by children, family conflict, impotence, fear of sexual intercourse, guilt, and disappointment (Shapiro & Kornfeld, 1989). Sears, Rodruge, Green, and Mills

(1995) studied 83 transplant recipients (mean age = 55.9) and found that trait anxiety was a significant predictor of increased symptom frequency and problems and decreased mental health.

In a study of long-term follow-up of cardiac transplantation, Jones, Taylor, Downs, and Spratt (1992) found that patients' depressive and anxiety symptoms decreased following transplantation while quality of life scores (based on the Nottingham Health Profile) increased. Bullinger, Angerman, and Kemkes (1992) reported long-term improvements in mood (less depression and anxiety) and quality of life (based on the 22-item Psychological General Well-being Index) for transplant recipients. Kugler, Tenderich, Stahlhut, and colleagues (1994) found that patients awaiting transplantation displayed high ratings of anxiety and depression. Following surgery, patients experienced significantly fewer anxious and depressive symptoms.

Mai, McKenzie, and Kostuk (1990) investigated psychological adjustment and quality of life in 27 heart transplant recipients (24 survivors) and found that prior to transplantation, 14 had psychiatric diagnoses. Four months following transplantation, 12 had psychiatric diagnoses. Pre-operative psychiatric diagnoses correlated with poor medical compliance following transplantation. Physical activity, employment, psychological adjustment, and sexual activity improved significantly following transplantation. Thus, they concluded that heart transplantation leads to substantial improvement in quality of life and psychosocial adjustment 12 months following surgery. However, there is little research examining long-term quality of life and psychosocial adjustment.

Functional Limitations. Functional limitations following heart transplantation include impairments in daily care activities (e.g., eating, self-care, and use of transportation), ability to lift objects, aggressive exercise, tiredness, loss of appetite, coughing, and swelling due to fluid retention, depression, altered mental status, and social restrictions (Houser, Konstam, & Konstam, 1992). Vocational limitations include regret over loss of work roles, income, social contacts, and self-perception (Houser et al., 1992).

Psychological Limitations. Psychological limitations include anxiety, depression, ambivalence, anger, and emotional lability (Houser, Konstam, & Konstam, 1992). Ambivalence is associated with difficulties in facing the seriousness of cardiac illness, fear of transplant, quality of life concerns, anxiety, and depressive symptoms (Kuhn, Myers, & Davis, 1988). The transactional and developmental framework for understanding adaptation to chronic illness includes the acute phase (ambiguity and uncertainty), the chronic phase (establishment of medical regimen), and the terminal/bereavement phase (recognition that the condition is beyond recovery) (Reiss & Kaplan De-Nour, 1989 cited in Houser et al., 1992).

In a longitudinal study of heart transplant patients, Dew, Roth, Schulberg, and colleagues (1996) found that pre-transplant psychiatric history, poor social support, use of avoidant coping strategies for coping with medical illness, and low-self-esteem predicted increased risk for psychiatric disorder (anxiety and depression) following cardiac transplantation. In a follow-up study of 191 transplant recipients evaluated up to three years post-transplant, Dew, Kormos, Winowich, and colleagues (2001) found that pre-transplant psychiatric history, female gender, longer hospitalization, impaired

physical functioning, and fewer social supports were cumulative risk factors for increased risk of psychiatric disorder post-transplant.

Compliance. In a study of 125 transplant recipients. Shapiro, Williams, Foray, Gelman, Wukich, & Sciacca (1995) found that substance abuse history, personality disorder, living arrangements, and global psychosocial risk were associated with compliance problems. In addition, global psychosocial risk was associated with rejection episodes and education inversely correlated with transplant coronary artery disease. Mai, McKenzie, and Kostuk (1990) found that psychiatric diagnoses correlated with poor medical compliance in 27 transplant recipients. Transplantation was associated with improvements in quality of life; physical activity, employment, and psychological adjustment improved six months following transplantation. In a study of post-transplant compliance with diagnostic tests (coronary angiograms, treadmill test, 24 hour Holter monitoring, radionuclide ventriculography, and 24 hour creatinine clearance) Grady and colleagues (1993) found that compliance ranged from 63% to 97% one year post-transplant. There was a trend for reduced compliance for diagnostic testing five years post-transplant; less than 80%. Demographic variables were not significantly related to compliance.

Predictors of Successful Cardiac Transplantation

In a study of 50 patients receiving cardiac transplantation, Bunzel and Wollneck (1994) investigated psychosocial predictors of successful surgery. Empathy, care and support by one partner, few demands for emotional communication, self-control, ability to cope with stress, emotional stability, high frustration tolerance, low aggression levels, and younger age predict successful cardiac transplantation. Social support from a partner

was the most salient predictor of success. Conversely, education, occupation, social status, indication for transplantation, length of stay in ICU, pre-operative anxiety and depression, and scores on Spitzer's quality of life index did not significantly predict clinical success.

Dew, Simmons, Roth, and colleagues (1994) examined psychosocial predictors of vulnerability to distress in the first year post-transplant for 72 transplant recipients. They found that patient's anxiety and depression levels were significantly elevated in the early post-transplant period but improved over time. However, anger-hostility symptoms were not elevated. Transplant recipients with a history of psychiatric disorder, younger age, lower social support, exposure to recent negative life events, poor self-esteem, poor sense of mastery, and use of avoidant coping strategies had higher levels of distress and poorer outcomes.

Historically, quality of life following cardiac transplantation improved due to the use of cyclosporine: a potent immunosuppressive agent (Cabrol, Gandjbackhch, Pavie, et al., 1992). Rejection is the main health risk for mortality following transplantation. Cyclosporine suppresses the "usual clinical, electrical, and hemodynamic symptoms of rejection," (Cabrol et al., 1992, p. 389). However, cyclosporine is not without side effects and complications such as chronic nephrotoxicity and elevated serum creatinine levels. The second major health risk factor for transplant recipients is occlusive coronary lesions or accelerated graft arteriosclerosis, which occurs in 25% of patients 5 years following transplantation. The three stages of accelerated graft arteriosclerosis include early inflammatory arteritis (between 3 and 8 months following transplant), late obliterative fibrous arteritis (2 years post-transplant), and late atherosclerosis (2 years

post-transplant).

Cognitive Functioning

The brain consists of 2% of total body weight, receives 15% of the cardiac output and 20% of the body's total oxygen consumption (Roman, Kubo, Ormaza, et al., 1997). Evaluation of patients before and after cardiac transplantation is a good model for evaluating decline in cognitive functioning due to heart failure. In addition, evaluation of patients receiving cardiac assist devices will help us to understand the effects of heart failure and left ventricular dysfunction.

Risk Factors for Decline in Cognitive Functioning

Cardiac surgery with cardiopulmonary bypass is associated with increased risk for complications in CNS functioning such as coma, seizures, hemiparesis, abnormal reflexes, and changes in memory functioning (Harter, Williams, George, & Mutchnick, 1990). Specifically, identification of disorientation during the early postoperative course (2-5 days post-surgery) is a critical predictor of verbal and spatial memory outcomes. In another study of self-reported cognitive functioning following cardiac surgery, Kareken, Williams, Muchnick, and colleagues (1992) found that risk factors (e.g., age and number of arteries bypassed) did not correlate with cognitive dysfunction. However, psychological distress was associated with memory loss and cognitive impairment. Vingerhoets, deSoete, and Jannes (1995) also found that higher levels of depression and state anxiety were associated with decline in cognitive functioning following cardiopulmonary bypass.

"Mesial temporal structures (including the hippocampus) may be particularly vulnerable to the adverse effects of hypoperfusion, because theses structures fall within the watershed areas where the vascularization is less robust and collateral circulation may

not be adequate," (Roman, Kubo, Ormaza, et al., 1997, p. 696). Recovery of memory deficits following transplantation implies that memory deficits are due to hypometabolism, which is reversible, in contrast to anoxic or vascular lesions, which cause permanent structural damage. Forty-two percent of patients undergoing cardiac bypass surgery show decline in mental ability five years later due to brain damage related to the surgery (Grady, 2001). However, decline in cognitive functioning may also be related to increasing age.

Neurologic Complications

Neurologic complications following cardiac surgery include becoming comatose and never regaining neurologic functioning again, stroke (0.8% to 5.2% incidence), delirium and confusion (10% incidence), and more commonly: disorientation, slowness awakening from anesthesia, and agitation requiring restraint (Borowicz, Goldsborough, Selnes, & McKhann, 1996). It is important to monitor cognitive status following cardiac surgery, particularly cardiac transplantation.

Neuropsychological Outcomes

Neuropsychological testing includes orientation and attention, perception, memory, verbal functions and language skills, construction, concept formation and reasoning, executive functions and motor performance (Lezak, 1995). Thus, evaluating patients before cardiac surgery and following cardiac surgery is imperative (Borowicz, Goldsborough, Selnes, et al., 1996). Many studies evaluated cognitive functioning following cardiac surgery in using different populations, different neuropsychological evaluation, different timelines of evaluation, and different definitions of cognitive change (see Borowicz et al., 1996 for a review).

Neuropsychological impairment is frequently associated with cardiac disease, open-heart surgery, and coronary artery bypass surgery (Bornstein, Starling, & Myerowitz, 1992). The high prevalence of neuropsychological impairment suggests diffuse cerebral dysfunction. They reported consistent correlations between neuropsychological impairment and cardiovascular function. Specifically, higher right atrium pressure correlates with neuropsychological impairments on Verbal IQ scores from the WAIS, Verbal Concept Attainment test, Visual Reproduction from the Wechsler Memory Scale, Trail Making A & B, Pegboard, and Tactual Performance Test. Conversely, better neuropsychological performance was associated with higher stroke/volume index and cardiac index.

Psychological investigations of heart transplant recipients include research on candidate selection and preoperative status, research on the psychological and neuropsychological sequelae of transplantation, and prospective research on the predictive nature of psychosocial and quality of life variables (see Strauss et al., 1992 for a review). They investigated psychosocial, neuropsychological and neurological status in 71 survivors of 100 heart transplants. Forty of the 71 completed extensive examination including EEG, auditory and visually evoked potentials, neuropsychological testing (i.e., the WAIS and Trail Making tests), and questionnaires concerning anxiety, depression, ways of coping, personality characteristics, and life satisfaction. They found that psychosocial and neuropsychological preoperative status did not significantly predict early postoperative complications. However, 25% of the patients had significantly higher levels of affective and neuropsychological impairment compared to the normal population.

Riether, Smith, Lewison, and colleagues (1992) found that 51 heart and 61 liver transplant recipients demonstrated significant improvements in neurocognitive functioning, depressive symptoms, and quality of life following transplantation. They suggested that structural or biochemical changes may explain neurocognitive improvements on the following measures: Mental Status Exam, California Verbal Learning Test, Wisconsin Card Sorting Test, and Trail Making Test. In a study of cognitive functioning and cardiopulmonary bypass surgery, Vingerhoets, Jannes, DeSoete, and VanNooten (1996) found that patients' performance on the Auditory Verbal Learning Test declined significantly immediately following surgery. However, six months later patients displayed significant improvement in long-term memory.

Cardiac Transplantation and Cognitive Functioning

Cardiac transplantation places patients at risk for central nervous system complication including difficulties related to the surgery itself, maintenance of the donor heart, function of the transplanted heart, and homograft rejection (Nussbaum & Goldstein, 1992). Cognitive side effects of cardiac transplantation include deficits in attention-concentration, organizational skills, verbal learning, abstract reasoning, psychomotor speed, concept formation, and cognitive flexibility and memory deficits. An ejection fraction of less than 20% correlates with difficulty organizing and learning new information. Clearly, cognitive functioning of transplant recipients is an important factor and predictor of medical compliance. Inability to follow the post-transplant medical regimen can lead to serious complications. Clinically, it is important to tailor treatment strategies based upon a patient's cognitive strengths and weaknesses.

Bornstein, Starling, Myerowitz, and Haas (1995) found preliminary evidence that cardiac transplantation may improve cognitive functioning. Patients with end stage heart failure experience impairments in memory, motor speed, and higher-level information processing. These cognitive deficits may be explained by low cardiac output, a prior neurologic event, emotional deficits, medications, or malaise associated with severe illness. Cardiovascular measures include right atrial pressure, left ventricular ejection fraction, pulmonary artery wedge pressure, cardiac index and stroke/volume index. Following transplantation, patients experienced significant cognitive improvements, however with limited clinical significance. Furthermore, neuropsychological deficits may be partially reversible by cardiac transplantation. In another study of cognitive functioning, Jones, Taylor, Downs, and Spratt (1992) reported significant improvement short-term memory, psychomotor speed, and mental arithmetic. These improvements may be explained by increased blood and oxygen supply to the brain as well as improved quality of life. Improvements in cognitive status predicted increased likelihood of patients returning to work.

In another study of transplant patients, Roman, Kubo, Ormaza and colleagues (1997) found that cardiac transplantation improved memory. Pre-transplant candidates had normal intelligence levels, attentional, language, and executive functioning despite impaired memory functioning although their memory improved significantly to normal levels following transplantation. Nussbaum and Goldstein (1992) reported that significant improvements in cognitive functioning do not occur following transplantation, whereas motor speed does improve significantly.

Schall, Petrucci, Brozena, Cavarocchi, and Jessup (1989) assert that cognitive functioning is a key determinant of quality of life in transplant recipients. Cognitive functioning determines the ability to manage the demands of daily living, follow a complex medical regimen, and adapt to the challenges imposed when resuming social and occupational roles, thus determining quality of life. However, they did not find significant improvement in cognitive functioning following cardiac transplantation on neuropsychological measures (54 completed pre-transplant evaluation and 20 completed follow-up evaluation), despite overall improvement in physical health.

Self-Report Assessment of Cognitive Functioning

Historically, self-report assessment has been an important part of neuropsychological assessment (O'Donnell, DeSoto, & DeSoto, 1993). Despite the unreliability of self-report measures accurately assessing actual behavior, memory self-assessment has much greater accuracy (Zelinski, Gilewski, & Thompson, 1980). For example, if you ask a patient: "How is your memory?" they will most likely tell the truth, whereas they might be inclined to give a socially desirable response to a more provocative question: "Have you ever felt down in the dumps due to your heart failure?" Metamemory, awareness of memory ability, is a significant factor impacting overall memory. Self-reported neurological symptoms ascertain only a patients' subjective self-perception of neurological impairment. Thus, collateral objective measures of neurological impairment are also necessary.

SUMMARY

The current study investigated quality of life and cognitive functioning in patients with cardiac assist devices awaiting cardiac transplantation. A review of the relevant literature on quality of life as well as cognitive and behavioral factors for these patients was provided. Quality of life is difficult to define and variously defined in the literature making it difficult to compare studies. Most research indicates that cardiac transplantation leads to improvements in quality of life across a variety of domains. However, there is little substantial research on quality of life and cardiac assist devices. Behavioral factors (e.g., psychiatric diagnoses) are important issues when considering transplant evaluation and have varying prevalence rates. Depression is the most salient in cardiac populations due to the high prevalence of Major Depressive Disorder and depressive symptoms and the interrelationship of cardiovascular disease and depression. In terms of cognitive factors, cardiac transplantation is associated with improvements in cognitive functioning (e.g., memory). However, the impact of cardiac assist devices on cognitive functioning is unknown. As cardiac assist devices improve hemodynamics (e.g., cardiac output and ejection fraction), they are expected to improve cognitive functioning and increase quality of life for end-stage heart failure patients. Thus, the current study will investigate the following hypotheses.

Hypotheses

Hypothesis 1

Mental Status (Mental Status Exam number of errors): ESHF inpatients will have fewer errors than MCAD candidates.

Hypothesis 2

Verbal Memory (Rey Auditory-Verbal Learning Test): ESHF inpatients remember more words than MCAD candidates.

Hypothesis 3

Visual Memory: ESHF inpatients will perform better than MCAD candidates on the Benton VRT and the Hooper VOT.

Hypothesis 4

Memory (Wechsler Memory Scale Memory Quotient): ESHF inpatients will have a greater memory quotient than MCAD candidates.

Hypothesis 5

Logical Memory (Wechsler Memory Scale Logical Memory Immediate & Delay): ESHF inpatients will perform better on Logical Memory than MCAD candidates.

Hypothesis 6

Visual Reproduction (Wechsler Memory Scale Visual Reproduction Immediate and Delay): ESHF inpatients will perform better on Visual Reproduction than MCAD candidates.

Hypothesis 7

Cognitive Processing Speed (Trail Making A & B): ESHF inpatients will take less time for Trail Making A & B than MCAD candidates.

Hypothesis 8

Motor Functioning: ESHF inpatients will tap more times for a 10 second trial and demonstrate greater grip strength with both hands than MCAD candidates.

Hypothesis 9

Depression will mediate the relationship between cognitive functioning and quality of life.

Hypothesis 10

Quality of life will improve after cardiac transplantation compared with quality of life with device.

CHAPTER 3

METHOD & PROCEDURES

The purpose of this study was to assess cognitive and psychosocial outcomes with cardiac assist devices. Specifically, this study evaluated quality of life, depressive symptoms, and cognitive functioning in patients receiving cardiac assist devices while awaiting cardiac transplantation.

Subjects

Participants were 53 cardiac assist device candidates and 298 end-stage heart failure inpatients.

Participant Inclusion Criteria. All potential (or previous) cardiac assist device recipients referred by Cardio-Throacic surgery at Hahnemann University Hospital, cardiac transplant recipients, and end-stage heart failure patients were included. Specific inclusion criteria included those that could read English at the 8th grade level, able to sit up in bed, not on a ventilator (saturation ratio > 90%), and those not on a nasal canula.

Participant Exclusion Criteria. Exclusion criteria included severe comorbid neurologic or psychiatric disorders, inability to read English at the 8th grade level, inability to sit up in bed, those on a ventilator (saturation ratio < 90%), those on a nasal canula, and those who chose not to participate.

Procedure

Patients completed pre-device and post-transplant cognitive and psychosocial evaluations as part of their hospital course. Upon admission to Inpatient Heart Failure/Transplant Unit or upon appointment in the Outpatient Cardiology Clinic,

participants completed the self-report questionnaires either in the waiting room or bedside. In addition, the psychosocial protocol was sent out via USMail to all device recipients from the last decade so they could complete questionnaires at home and return them to the clinic.

Psychosocial Evaluation. Psychosocial evaluation included administration two quality of life measures (Kansas City Cardiomyopathy Questionnaire and the Medical Outcomes Study Short Form-36), a depression inventory (BDI-II), the Memory Questionnaire (MQ), and the Neuropsychological Impairment Scale (NIS). Because questionnaires were administered at one point in time, subjects were at different time periods in their treatment. Questions were phrased to assess the patient's responses to each item "before your heart failure," "with your cardiac assist device", and "following cardiac transplant."

Cognitive Evaluation. Cognitive evaluation included administration of the following neuropsychological measures: Wechsler Memory Scale, Bender Gestalt Test, Reitan-Indiana Aphasia Screening Test, Rey Auditory-Verbal Learning Test, Trails A & B, Benton Visual Retention Test, Finger Tapping, and Grip Strength.

Retrospective Assessment. Retrospective assessment of prior cardiac assist device and transplant recipients included mailing of the psychosocial questionnaires. Participants who chose to participate in this part of the study signed the consent form, completed the questionnaires, and returned a copy of the consent form and the questionnaires via USMail. The purpose of this retrospective assessment was to provide meaningful comparisons and norms for this end stage heart failure population receiving cardiac assist devices and transplantation.

Measures

Quality of Life

Kansas City Cardiomyopathy Questionnaire (KCCQ). The KCCQ is a reliable and valid 23-item self-report measure of quality of life for patients with congestive heart failure (Green, Porter, Bresnahan, & Spertus, 2000; Spertus et al., 2002).[1] The KCCQ assesses physical limitations, symptoms, self-efficacy, social interference, and quality of life. The KCCQ has adequate reliability and convergent validity: r=0.46 to 0.74, p <.0001 with congestive heart failure patients (ejection fraction <40).

Medical Outcomes Study Short-Form 36 Health Survey (SF-36). The SF-36 assesses eight components of health status including 1) physical functioning, 2) role limitations, 3) bodily pain, 4) social functioning, 5) general mental health (psychological distress and psychological well-being), 6) role limitations, 7) vitality (energy/fatigue), and 8) general health perceptions (Ware & Sherbourne, 1992). The scale also includes a mental component summary and a physical component summary. The SF-36 has acceptable reliability and validity (Ware & Sherborune, 1992) and has recently been used with cardiac populations (Brown, Melville, Gray, Young, Skene, & Hampton, 2000).

Depression

Beck Depression Inventory II (BDI-II). The BDI-II is the most prominently and frequently cited self-report measure of depression (Beck, 1967; Beck, Steer, & Brown, 1996; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The 21-item questionnaire assesses four major components of depression: behavioral, affective, cognitive, and physiological. Numerical values assigned to each statement range from 0 to 3 indicate increasing severity. For example, Item 1 includes the following statements: I do not feel

sad (0), I feel sad (1), I am sad all the time and I can't snap out of it (2), and I am so sad or unhappy that I can't stand it (3). Total BDI-II scores, indicating severity of depression, range from 0 to 63. According to Beck's clinical criterion, a score less than 4 indicates minimal depression, between 5 and 13 mild depression, between 14 and 20 moderate depression, and above 21 severe depression. The BDI-II is a valid measure of depression for both psychiatric and normal samples with good internal consistency (alpha = .81) and stability coefficients in the .70 range. The BDI consistently and significantly correlates (ranging from .60 to .90) with clinical ratings of depression (Shaver & Brennan, 1991; see Sears, Rodrigue, Sirios, Urizar, & Perri, 1999 for norms for cardiac patients).

Cognitive Functioning

The Neuropsychological Impairment Scale (NIS). O'Donnell, DeSoto, DeSoto, and Reynolds (1994) developed the NIS, a self-report measure of neuropsychological symptoms. Historically, self-report assessment has been an important part of neuropsychological assessment. For example, Halstead developed a Head Injury Questionnaire and memory has been commonly assessed by self-report. The NIS contains 95 items assessing neuropsychological symptoms (80 items), affective disturbance (10 items), and test-taking attitudes (5 items). Items are rated on a 5-point Likert scale ranging from not at all (0) to 4 extremely (4). NIS scores consist of three summary scores: the Global Measure of Impairment Index (sum of 80 items), Total Items Checked (number of neuropsychological items with scores greater than zero), and Symptom Intensity Measure (ration of GMI/TIC). The NIS also includes an observer report form, which allows primary caregivers to describe how they perceive the patient.

NIS scores correlate with other neuropsychological tests of cognitive impairment and has adequate and reliability and validity (O'Donnell, DeSoto, & DeSoto, 1993). Research indicates that patients rate their academic skills and speech/language functioning more accurately than their memory, attention, and higher level problem solving abilities.

Neuropsychological Evaluation

The neuropsychological evaluation was consistent with the protocol given to heart transplant patients for the past 18 years to follow suit and afford comparisons between new data and old data from similar patients. For example, the original Wechsler Memory Scale was used as opposed to the Wechsler Memory Scale-III.

Verbal Memory

Rey Auditory-Verbal Learning Test (Rey AVLT). The Rey AVLT assesses immediate memory span, practice effects, as well as retroactive and proactive interference (Rey, 1964). Patients are instructed to recall a list of 15 words including 5 presentations of the words, a distracter trial, and delayed memory recall of the original list of 15 words. The examiner records the order in which the patients recall the words to measure their pattern of recall.

Benton Visual Retention Test (BVRT). The BVRT assesses visual-perceptual ability, constructional skills, and immediate visual memory (Benton, 1974). Patients are instructed to reproduce abstract geometric designs from memory. Scoring includes counting total number of designs drawn correctly and the total number of errors. Types of errors include omissions and additions, distortions, preservations, rotations,

misplacements, and size errors. Youngjohn, Larrabee, and Crook (1993) provide adult age- and education-correction norms for the BVRT.

Memory

Wechsler Memory Scale (WMS). The WMS includes assessment of personal and current information, mental control, logical memory, digit span, visual reproduction, associate learning, and delayed logical memory, visual reproduction, and associate learning (Wechsler, 1987). Poor performance on the WMS corresponds with memory disorders and left hemisphere lesions in particular (Lezak, 1995).

Visual Memory

Hooper Visual Organization Test (HVOT). The Hooper VOT was originally developed to identify patients with organic brain conditions (Hooper, 1983; Lezak, 1995). Patients are presented with thirty pictures of "cut up" objects and asked to identify them. Scores range from 0 to 30 (one point for each correct identification of the picture). Scores under 20 indicate organic brain pathology.

Language

The Reitan-Indiana Aphasia Examination assesses language disorders and left hemisphere dysfunction. Tasks include ability to name objects, read, write, copy objects, and recognize numbers and letters. Greater than 6 errors indicate brain injury.

Cognitive Processing Speed

The Halstead Reitan Battery includes two measures of attention and cognitive processing speed: Trail Making A and B (Halstead, 1947).

Trail Making A. Trail Making A consists of 25 (numbered from 1 to 25) circles on a sheet of paper. The patient is instructed to "connect the dots" in ascending

numerical order. The amount of time for completion and the number of errors are recorded. Performance in less than 39 seconds indicates impairment.

Trail Making B. Trail Making B consists of 25 (numbered from 1 to 13 and lettered from A to L) circles. The patient is instructed to "connect the dots" alternating numbers and letters (e.g., 1A, 2B, 3C, etc.). Trail Making B tests recognition of numbers and letters, ability to find the correct number or letter, and time pressure. Completion in less than 91 seconds indicates impairment.

Motor Functioning

The Haltead Reitan Battery includes two measures of motor functioning: finger tapping and grip strength (Halstead, 1947).

Finger Tapping. The Finger Tapping test measures fine motor control, kinesthetic ability, motor speed, and visual-motor coordination. Patients were instructed to tap their forefinger of both their dominant and nondominant hands (separately) on a key on a small clipboard. Patients typically perform better with the dominant hand. Completion of less than 61 taps with the dominant hand indicates impairment, whereas less than 46 taps with the nondominant hand indicates impairment. However, better performance with the dominant hand by 15-20% or more indicates impairment of the nondominant hand.

Grip Strength. Patients were instructed to grip the handle of a device measuring grip strength first with their dominant and then with their nondominant hand. Strength of less than 40 kg with the dominant hand indicates impairment, whereas less than 35 kg with the nondomaint hand indicates impairment.

Data Analysis

The first 8 major hypotheses regarding cognitive functioning required a series of t-tests to compare the ESHF inpatients and MCAD candidates. ESHF inpatients were expected to perform better than the MCAD candidates on the Mental Status Exam (make fewer errors), Rey Auditory-Verbal Learning Test, Benton Visual Retention Test, Hooper Visual Organization Test, Wechsler Memory Scale (have higher Memory Quotients), Logical Memory Immediate and Delay (remember more word phrases), Visual Reproduction Immediate and Delay, Trail Making A & B (have quicker cognitive processing speed), and motor functioning (perform better on finger tapping and grip strength).

Depression was hypothesized to mediate the relationship between self-reported neurological impairment and quality of life. A series of regression analyses followed by a partial correlation tests for mediation (Baron & Kenny, 1986). Finally, the hypothesis that quality of life will improve following cardiac transplantation compared with quality of life with device required a one-way analysis of variance.

CHAPTER 4

RESULTS

Demographic Information

Neuropsychological data was collected on 53 (28 male/25 female) cardiac assist device candidates (MCAD). The age range for this group was between 21 and 69 (mean = 51.9). Etiology included 23 ischemic, 25 idiopathic, and 5 other. Neuropsychological data was also obtained for 298 (245 male/53 female) end-stage heart failure (ESHF) patients. For the ESHF group, age ranged between 17 and 68 years (mean = 49.42). Etiology included 153 ischemic, 100 idiopathic, 10 structural, 25 congenital, 1 viral, and 1 other. There were no significant differences in age, gender, or etiology of heart failure between the two groups (Table 5).

Neurological Events

Of the 53 MCAD candidates (8 TCI, 8 Abiomed, 8 Novacor, and 14 onto OHT), several experienced pre-surgical neurological events such as a loss of consciousness following a motor vehicle accident, circulation problems, left-sided weakness, multiple Transient Ischemic Attacks and symptoms, and a right cerebrovascular event. In order to meet criteria for a neurological event, neurological symptoms had to warrant medical attention. Of the 53 MCAD candidates, 14 experienced post-surgical neurological events including cerebrovascular events, brainstem cerebrovascular events, delirium, hemiplegia, and Transient Ischemic Attacks.

Of the 602 end-stage heart failure patient, 53.3% (339) had no pre-neurological events, 18.1% (109) had 1 pre-event, 3.5% (21) had 2 pre-events, .2%(1) had 3 pre-

events, .2% (1) had 4 pre-events, and .2% (1) had 8 pre-events. Of the 602 ESHF patients, 53.7% (323) had no post-neurological events, 12.6% (76) had 1 post-event, .3% (2) had 2 post-events, .2% (1) had 3 post-events, .2%(1) had 4 post-events, and 1.3% (8) had 9 post-events.

Comparing ESHF and MCAD Candidates

Cognitive functioning overall was better for end-stage heart failure patients (ESHF) than for cardiac assist device candidates (MCAD) across most cognitive domains, with the exception of the Mental Status Exam, Visual Reproduction subtest of the Wechsler Memory Scale, and grip strength task. A series of t-tests with Bonferonni adjusted alpha levels compared the two groups on all cognitive measures and the two groups were significantly different across all cognitive domains ($p < .001$; see Table 6).

Hypothesis 1: MSE. A t-test indicated that the ESHF group (1.99 errors) had a greater number of errors than the MCAD group (.75 errors) on the Mental Status Exam: $t(11, 243) = 3.45$, $p < .005$.

Hypothesis 2: Verbal Memory. ESHF inpatients remembered more words than MCAD candidates on the Rey Auditory-Verbal Learning Test. A t-test indicated that the ESHF group remembered significantly more words than the MCAD group on all trials. The ESHF group remembered an average of 41.27 words, whereas the MCAD group remembered an average of 37.49 words: $t(34, 131) = 20.34$, $p < .001$. The results for individual trials are presented in Table 7.

Hypothesis 3: Visual Memory. On the Benton Visual Retention Test, the ESHF group performed better than the MCAD candidates. The ESHF group (6.27 correct) drew more items correctly than the MCAD group (4.92 correct): $t(12, 147) = 7.75$, $p < .001$.

In addition, the MCAD group had more errors (7.08 errors) than the ESHF group (5.81 errors): t (12, 148) = 6.12, $p < .001$.

On the Hooper Visual Organization test, the ESHF group (24.82) obtained more items correct than the MCAD group (22.92): t (12, 181) = 30.19, $p < .001$.

Hypothesis 4: Memory. On the Wechsler Memory Scale, the ESHF inpatients (103.54) had a great memory quotient than the MCAD candidates (97.85): t (12, 160) = 25.33, $p < .001$.

Hypothesis 5: Logical Memory. On the Logical Memory subtest of the WMS, the ESHF group (7.25) performed better than the MCAD group (6.29): t (25, 167) = 15.60, $p < .001$. The ESHF group (5.16) also performed better than the MCAD group (4.63): t (22, 162) = 7.89, $p < .001$.

Hypothesis 6: Visual Reproduction. On the Visual Reproduction (Immediate) subtest of the WMS, the MCAD group performed better than the ESHF group (8.07): t (24, 165) = 10.02, $p < .001$. The ESHF group (6.30) performed better than the MCAD group (5.72) on the Visual Reproduction (Delayed) subtest: t (22, 160) = 6.11, $p < .001$.

Hypothesis 7: Cognitive Processing Speed. The ESHF group (48.19 seconds) took less time to complete Trails A than the MCAD group (68.23 seconds): t (12, 168) = 6.18, $p < .001$. In addition, the ESHF group (102.57 seconds) took less time to complete Trails B than the MCAD group (119.25 seconds): t (11, 167) = 9.84, $p < .001$.

Hypothesis 8: Motor Functioning. Results on the grip strength task were contrary to the original hypothesis. On the grip strength task with the dominant hand, the ESHF group (33.00 kg) was stronger than the MCAD group (31.25 kg): t (12, 110) = 14.50, $p <$

.001. On the grip strength task with the non-dominant hand, the MCAD group (31.57 kg) was stronger than the ESHF group (30.69 kg): t (12, 109) = 17.27, $p < .001$.

On the finger tapping task with the dominant hand, the ESHF group (44.93) performed better than the MCAD group (41.18): t (14, 127) = 15.86, $p < .001$. With the non-dominant hand, the ESHF group (40.26) performed better than the MCAD group (38.52) on finger tapping: t (14, 127) = 18.04, $p < .001$.

Quality of Life Data

Thirty-three questionnaires were mailed out to cardiac assist device recipients living at home post-transplant. After two sets of reminders (including a reminder letter from their attending physician), a total of 17 questionnaires were ultimately obtained (51.52% return rate). Several questionnaires were completed in the hospital by inpatients as well. The total number of completed quality of life questionnaires was 23 cardiac assist device candidates with time period in parentheses.

Quality of Life

KCCQ Scores. Overall, the KCCQ had high internal consistency from this sample with an internal alpha of .96. First, KCCQ sum scores were computed by summing all items on the KCCQ as a composite measure of quality of life. Sum scores ranged from 30 to 116 with a mean of 78.57, (SD = 27.84). Spertus, Tooley, Jones, and colleagues (2002) divided baseline KCCQ sum scores into four ranges: 0-24, 25-49, 50-74, 75-100.

Two subscale scores for the KCCQ were computed: Activity Limitation and Symptom Presence. Activity Limitation scores included patients' rankings of 1 (extremely limited), 2 (quite a bit limited), 3 (moderately limited), 4 (slightly limited), 5

(not at all limited), and 6 (limited for other reasons or did not do the activity) of the following activities: dressing yourself; showering/bathing; walking 1 block on level ground; doing yardwork, housework or carrying groceries; climbing a flight of stairs without stopping; hurrying or jogging (as if to catch a bus); hobbies, recreational activities; working or doing household chores; visiting family or friends outside of your home; and intimate relationships with loved ones. KCCQ Activity scores, based on 10 items, ranged from 10 to 53 with a mean of 33.13 (SD – 15.62). Thus, higher scores indicate greater activity limitation, whereas lower scores indicate less activity limitation.

Symptom presence scores for the KCCQ required patients' rankings of 1 (extremely bothersome), 2 (quite a bit bothersome), 3 (moderately bothersome), 4 (slightly bothersome), 5 (not at all bothersome), and 6 (no symptom present) of the following symptoms: shortness of breath; fatigue, or ankle swelling; swelling in your feet, ankles, or legs; swelling in your feet, ankles, or legs when you woke up in the morning; fatigue bothering you; fatigue limiting your activities; shortness of breath bothering you; shortness of breath limiting your activities; shortness of breath causing you to sleep upright in a chair; felt discouraged or down in the dumps because of your heart failure?; how much has your heart failure limited your enjoyment of life? Thus, higher scores indicate greater symptom distress, whereas lower scores indicate less symptoms distress. KCCQ symptom scores, based on 10 items, ranged from 10 to 60 with a mean of 34.95 (SD = 13.93).

SF-36 Scores. The SF-36 had reasonable internal consistency for this sample with an alpha value of .57. First, SF-36 sum scores were computed by summing all items on the SF-36, providing a composite quality of life score. Two subscale sum scores were

computed for the SF-36 including Sf-36 Activity and SF-36 Pain/Distress. SF-36 Activity scores required patients to rank 1 (limited a lot), 2 (limited a little), and 3 (not limited at all) the following 10 activities: vigorous activities; moderate activities; lifting or carrying groceries; climbing several flights of stairs; climbing one flight of stairs; bending, kneeling, or stooping; walking more than a mile; walking several blocks; walking one block; and bathing or dressing yourself. Higher scores indicate greater ability to engage in activities, whereas lower scores indicate greater activity limitation.

SF-36 Pain/Distress scores required patients to rank 1 (not at all), 2 (slightly), 3 (moderately), 4 (severe), and 5 (very severe) the following 12 questions: How much bodily pain have you had?; How much did pain interfere with your normal work (including both work outside the home and housework)?; Did you feel full of pep?; Have you been a very nervous person?; Have you felt so down in the dumps that nothing could cheer you up?; Have you felt calm and peaceful"; Did you have a lot of energy?; Have you felt downhearted and blue"; Did you feel worn out?; Have you been a happy person?; and Did you feel tired? Higher scores indicate greater pain/distress, whereas lower scores indicate less pain/distress.

Depressive Symptoms

BDI II Scores. BDI II total scores ranged from 0 to 37 (Mean = 11.78, SD = 9.00). Depressive symptoms (total BDI score) correlated positively with neuropsychological impairment (NIS total): $r = .78$, $p < .01$ and negatively with quality of life (KCCQ sum): $r = -.65$, $p < .05$.

Self-Reported Neurological Impairment

NIS Scores. NIS total scores ranged from 15 to 60 (Mean = 57.35, SD = 33.03). Higher scores indicate greater self-reported neuropsychological symptoms. For the purposes of quality of life analyses, cognitive functioning was operationalized by self-reported neuropsychological impairment

Correlations

Correlations between depressive symptoms, neuropsychological impairment, and quality of life are shown in Table 8. There was a significant positive correlation between BDI total scores and NIS total scores: $r = .79$, $p < .01$ and significant negative correlation between BDI total scores and quality of life (KCCQSUM): $r = -.65$, $p < .05$. In addition, there was a significant negative correlation between BDI total scores and KCCQ Pain/Distress: $r = -.69$, $p < .01$ and a significant positive correlation between BDI total scores and SF-36 Pain: $r = .50$, $p < .05$. NIS total scores have an inverse relationship with KCCQ Pain/Distress: $r = -.54$, $p < .01$.

Hypothesis 9

Depression was hypothesized to mediate relationship between cognitive functioning and quality of life. A series of univariate regression analyses followed by a partial correlation (Baron & Kenny, 1986) tested this mediational hypothesis. First,

cognitive functioning (NIS total scores) was correlated with depression: $r = .79$, $p < .01$ and quality of life (KCCQSUM): $r = -.50$, NS. Then, cognitive functioning was correlated with quality of life while controlling for depressive symptoms: $r = -.07$, NS. This data fails to suggest that cognitive functioning mediates the relationship between depression and quality of life with these variables.

Hypothesis 10

Quality of life will improve after cardiac transplantation compared with quality of life with device. To test for significant differences, a one-way analysis of variance using KCCQSUM scores was performed. Results indicated that there were significant differences between the groups (ESHF, Device, and OHT): $F(2, 11) = 8.20$, $p < .01$.

A Multivatiate Analysis of Variance was also performed to use all quality of life subscales; KCCQ Activity, KCCQ Pain, SF-36 Activity, and SF-36 Pain. Results indicated there were significant differences between the groups: $F = 6.1$, $p < .05$. Adjusted R Squared values (indicating variance accounted for) were as follows: .48 for KCCQ Activity, .28 for KCCQ Pain, .34 for SF-36 Activity, and -.13 for SF-36 Pain.

Gender Analyses

Follow-up analyses compared men and women on quality of life data. One-way ANOVAs did not yield significant differences between men and women.

CHAPTER 5

DISCUSSION

Cognitive functioning, quality of life, and emotional well-being are salient factors in the lives of end-stage heart failure patients receiving cardiac assist devices or transplants to prolong their life. The present study provided a description and analysis of this fragile population: quality of life and quality of dying. The focus was two-fold: 1) to compare cognitive functioning of ESHF and MCAD candidates and 2) to describe quality of life in relation to depressive symptoms, neuropsychological impairment, cognitive functioning, and status (e.g., ESHF, MCAD, or OHT). Overall, results were consistent with the current literature on end-stage heart failure patients. Results also provided new additional information not currently available in the literature on patients receiving cardiac assist devices in comparison to end-stage heart failure inpatients.

Cognitive Functioning

Overall, cognitive results were not surprising. However, there were several unusual findings, which warrant explanation. As predicted, ESHF inpatients performed better than MCAD candidates on most cognitive measures. Because MCAD candidates were "sicker" than ESHF inpatients, MCAD candidates' cognitive functioning was expected to be more declined. Results indicated that ESHF patients had better verbal memory, visual memory, overall memory (Memory Quotient), Logical Memory, cognitive processing speed, and finger tapping speed than MCAD candidates.

Contrary to original hypotheses, MCAD candidates performed better than ESHF inpatients on the Mental Status Exam, Visual Reproduction subtest of the Wechsler

Memory Scale, and grip strength task. ESHF inpatients made more errors than MCAD candidates on the Mental Status Exam. Although this difference may not be clinically significant, it is certainly curious. The difference could be due to the measure or the differing mental status of the groups. Although the MCAD candidates performed better than ESHF inpatients on the Visual Reproduction Immediate, they did not perform better on the Visual Reproduction Delay subtest. Differences in gender or artistic ability may explain this finding. Finally, MCAD candidates performed better than the ESHF inpatients on the grip strength task for the nondominant hand. This may be due to the placement of IntraVenous lines in these patients, hindering performance or differences in grip strength between the groups due to gender although the MCAD group had more females than the ESHF group.

Quality of Life

Results of the current study indicated that there is a significant positive relationship between depressive symptoms and neuropsychological impairment and a significant negative relationship between depressive symptoms and quality of life. There was also a significant negative correlation between depressive symptoms and KCCQ Pain/Distress and a significant positive correlation between depressive symptoms and SF-36 Pain scores. Self-reported neurological symptoms had an inverse relationship with KCCQ Pain/Distress scores. Results did not support the hypothesis that cognitive functioning mediates the relationship between depression and quality of life. In addition, follow-up analyses indicated there were no significant gender differences for quality of life data.

Overall, these results are consistent with the sparse current literature. In a recent study of quality of life and cognitive status, Dew and colleagues (2001) found that patients with ventricular assist devices had poorer cognitive status and were less likely to return to work than non VAD patients. However, this study did not include a complete neuropsychological evaluation and therefore did not determine precise levels of cognitive impairment. Dew and colleagues also purport that cognitive impairment leads to reductions in daily functioning and quality of life.

In an empirical evaluation of quality of life in 2 cardiac assist device recipients (outpatients while awaiting OHT), Dew, Simmons, Roth, Schulberg, Thompson, Armitage, and Griffith (1994) found that physical functional well-being, psychological well-being, and social functioning, was similar to other heart transplant candidates without devices.

Limitations to Current Study

The major limitation of this study is the small sample size of cardiac assist device recipients. Despite the discrepancy in sample sizes of the two groups being compared, equal variances within the two groups were assumed allowing for meaningful comparisons. The small sample size of MCAD candidates is due to the fragility and mortality of the population. When heart failure patients become candidates for cardiac assist devices, it is a last resort for prolonging their lives. They are critically ill and unstable hemodynamically; "long-term treatment if critically ill patients is admittedly burdened by a high in-hospital and early follow-up mortality," (Isgro, Skuras, Kiessling, Lehmann, & Saggau, 2002, p. 100). The median survival time is 30 days or less without transplantation with an overall life expectancy estimation of 6-9 months (Thompson &

Shapiro, 1994). With transplantation, the survival rate is 80% for one year and 70% for 5 years. Furthermore, deconditioning, sleep and sensory deprivation contribute to their altered mental status and adjustment difficulties. Even if they do survive, it is very difficult to get them to complete cognitive evaluations or self-report questionnaires. The small amount of data collected is valuable and novel to this line of research.

Defining Quality of Life. The major challenge of quality of life research with this population is defining quality of life. This study operationalized quality of life with disease-specific and general health related quality of life measures. The disease-specific measure assessed activity limitation and symptom presence related to congestive heart failure. The general health related quality of life measure assessed how much health problems have limited activities and pain and psychological distress.

Future Research

Future research should continue to assess both cognitive functioning and quality of life of MCAD recipients including the new and permanent devices such as the AbioCor Total Artificial Heart for biventricular replacement. New left ventricular assist devices include the HeartMate, Novacor, Arrow LionHeart LVD-2000, and HeartSaver. Left ventricular replacement devices include the HeartMate, Novacor, Arrow LionHeart LVD-2000, and HeartSaver. Continuous-flow left ventricular assist devices include the HeartSaver, Jarvik 2000, MicroMed DeBakey, and the HeartMate II. Assessments should also be conducted at various time periods, although the challenge of conducting multiple assessments with this population is well known.

Recently, the Randomized Evaluation of Mechanical Assistance Therapy as an alternative in Congestive Heart failure (REMATCH) trial has shown a "clear benefit in

terms of survival and improved quality of life. MCS should therefore no longer be considered as simply a temporary bridge to other therapies, but also a destination therapy whose potential should continue to expand through the development and use of newer, more innovative devices such as continuous flow pumps, next-generation centrifugal pumps, and total artificial hearts," (Frazier, 2002, p. 178).

CONCLUSIONS

This study has provided invaluable information about cognitive functioning and quality of life with MCAD candidates. However, much remains unknown about the specific effects of the different devices and Inotropic support precisely on cognitive functioning and the subsequent impact on quality of life. Future research should aim to refine the relationship between cognitive functioning and quality of life with this fragile population over several time periods (i.e., pre-, peri-, and post-transplant). However, the reality of obtaining such data is extremely difficult. Perhaps funding would help, but the expedience of collecting neuropsychological data in the intensive care unit will still remain a challenge.

In summary, the major findings of the study were:

1) These patients are resilient in comparison to the general population; their cognitive functioning was actually in the normal range and they were not depressed. This fits well into the health psychology literature of human resiliency in response to disease and adversity. Clinical psychologists look for and seek to implement positive changes in people.
2) There was a strong relationship between self-report depressive symptoms and self-reported neurological impairment.

Footnote

[1]Dr. John Spertus, MD, MPH granted copy permission of use of the KCCQ for this project.

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Table 1

Survival Statistics for Cardiac Transplantation

2,000 transplants annually

Median waiting time: 226 days

20-40% of candidates died while waiting in 1996 (Savage & Canody)

30-40% of transplant candidates expire due to hemodynamic instability while waiting donor hearts.

Heart transplant recipients	**74% male**
	78% white
	20% between the ages of 35 and 49
	50% were between the ages of 50 and 60 (American Heart Association)
1 year survival rate	**80%** (McGee & Horgan, 1996)
	83%(NIH)
	85% (Levensen & Olbrischk, 1993)
	85.7% (between 1996 and 1997) (American Heart Association)
2 year survival rate	**78%** (NIH)
3 year survival rate	**76.7%**(American Heart Association)
	74% (NIH)
4 year survival rate	**71%** (NIH)
5 year survival rate	**72%** (McGee & Horgan, 1996)

70-82% (Walter, Mohan, & Dahan-Mizrahl, 1992; Shapiro, 1992)

75% (Levensen & Olbrisch, 1993)

70% to 80% (Shapiro, 1996).

25% suffer diffuse coronary atherosclerosis (Walter et al.)

10 year survival rate

74% (Walter, Mohan, & Dahan-Mizrahl, 1992; Shapiro, 1992)

Survival rates for patients on inotropes (epinephrine, dobumatmine, dopamine, & milrinone)

2% (no inotropes)

3% (low-dose inotropes)

7.5% (moderate-dose)

21% (one-high-dose)

42% (two-high-dose)

80% (three-high-dose) (Samuels et al., 1999).

Table 2

Cardiac Assist Devices

Bridges to Recovery	Bridges to Transplantation	Alternative to transplantation
Intraortic Balloon Pump Abiomed BVS 5000	Thoratec TCI HeartMate I (pulsatile) TCI HeartMate II (axial) TCI HeartMate III (centrifugal magnetic) NASA-Debakey Jarvik 2000 LVAD Arrow-Lionheart	TCI HeartMate Arrow Lionheart (magnetic)

Device Support Ranges	Energy Source	Pump Position	Flow Characteristics
short-term	Pneumatic	extra-corporeal	Pulsatile
intermediate-term	Electric	para-corporeal	Centrifugal
long-term	Alternative	Implantable	Axial
	(nuclear or ionic)		
	Skeletal muscle power (i.e., latissimus dorsi)		
	Farrar, Riechenbach, & Hill, 1995)		

HeartMate (Thermo Cardisystems, Inc, Woodburn, Mass) Left Ventricular Assist Device

long-term

implantable

electric device

textured surface (facilitates the forming of biological lining, a psuedo-neointima), does not require anticoagulation; aspirin is sufficient

FDA approved HeartMate pneumatic in 1994

Abiomed BVS 5000 (Abiomed, Inc., Danvers, Mass.)

short-term (days to weeks) bridge to recovery

extracorporeal, pulsatile, pneumatic device with a smooth surface (requires anticoagulation)

Automatic pulsatile pump

pumps 4.5-6.5 L/min

Provides univentricular or biventricular support with dual chamber design

Supports left or right side of the heart (or both)

Right-sided support, the device draws blood from the right atrium and returns blood to the pulmonary artery

Left sided support, the device draws blood from the left atrium and returns blood to the aorta

Patients are bed bound

FDA approved as rescue-to-recovery only

Patients with the Abiomed device reported better quality of life than medical management (inotropes) but less than transplant (Petrucci et al., 1999).

Novacor (Novacor Division, Baxter Healthcare Corp. Oakland, CA)

long-term (months to years) support

implantable, electric, and pulsatile with a smooth surface, thereby requiring anticoagulation (i.e., coumadin).

includes an implantable blood pump, electromagnetic energy converter, and an extracorpal computer control

high rate of thromboembolic complications (DiBella et al., 2000)

Device Complications With the Novacor LVAS

inflow valve regurgitation
inflow canula obstruction
outflow valve regurgitation
outflow canula obstructon)
cardiac tamponade (Lavee et al., 1990)
lead to changes in perfusion pressures and filling rate and ejection rate (Mandarino et al., 1990).

Thoratec VAD

provides adequate circulatory support for more than 30 days despite left atrial or left ventricular cannulation (Holman et al., 1995).

left atrial cannulation causes more neurologic events than left ventricular canulation (Holman et al.).

Perioperative Survival Rates Are High

efficient LVAD (decompresses the left heart effectively)

mean pulmonary capillary wedge pressure of 1mm Hg

low pulmonary vascular resistances

low transpulmonary pressure gradients (Koul et al).

Postoperative Complication Rate Are High

fragile condition of the patients and the device itself

Biological valve dysfunction

post-LVAD right heart failure (19% of patients) (Koul et al.).

Early Device Complications

Hemorrhage at implantation

Right side heart failure

Air embolism

Multisystem organ failure

Late Complications (greater than 30 days)

Device failure (Goldstein, Oz, & Rose, 1998).

Infection (Goldstein, Oz, & Rose, 1998; Griffith et al., 1996)

Thromboembolism: 20-30%

HeartMate has demonstrated reduced thrombolembolic events of only 4%, (Reilly et al., 2000)

Abnormalities in Blood Rheology Explaining Device Complications

increases in blood viscosity

erythrocyte rigidity

fibrinogen concentration

platelet aggregation explain some device complications (Hung et al., 1989).

Table 3

Demographic Information for ESHF and MCAD Candidates

	ESHF Inpatients	MCAD Candidates
N	298	53
Gender	245m/53f	28m/25f
Age	49.42(17-68)	51.9(21-69)
Education	12.55(5-22)	12.55(9-18)
Etiology:		
Ischemic	153	23
Idiopathic	100	25
Structural	10	0
Congenital	25	0
Other	10	5

Table 4

Comparing Cognitive Functioning for ESHF and MCAD Candidates

	298 ESHF Mean (SD)	MCAD Mean (SD)
MSE # errors	1.98 (2.11)	.75 (1.16)
Benton C	6.27 (.10)	4.92 (2.05
Benton E	5.81 (.21)	7.08 (3.40)
Trails A (seconds)	48.2 (1.12)	68.2 (37.95)
Trails B (seconds)	102.6 (3.58)	119.2 (69.66)
Grip Strength (D)	33.0 (.67)	31.2 (8.19)
Grip Strength (ND)	30.7 (.63)	31.6 (8.94)
Finger Oscillation (D)	44.9 (.51)	41.2 (10.09)
Finger Oscillation (ND)	40.3 (.44)	38.5 (9.13)
Hooper	24.82 (.19)	22.92 (3.37)
WMS MQ	103.54 (1.02)	97.85 (13.63)
WMS LM	7.3 (.17)	6.3 (2.06)
WMS LM-d	5.2 (.17)	4.7 (2.81)
WMS VR	8.1 (.19)	9.4 (4.67)
WMS VR-d	6.3 (.21)	5.7 (4.48)

* $p < .05$, one tailed

** $p < .01$, one tailed

Table 5

Comparing Rey Auditory-Verbal Learning Task Performance for ESHF and MCAD Candidates

Trial	ESHF	MCAD	t	df	p
1	5.34	4.46	10.31	12, 139	001
2	7.58	6.61	10.40	12, 140	001
3	8.81	8.31	9.44	12, 140	001
4	9.83	7.00	7.55	12, 140	001
5	10.45	8.54	7.79	12, 140	001
B	5.04	3.92	8.54	12, 140	001
6	8.15	5.85	5.97	12, 140	001
Total	42.37	37.49	20.34	34, 131	001

* $p < .05$, one tailed

** $p < .01$, one tailed

Table 6

Quality of Life Scores (N=23)

Measure	Range	Mean	SD
KCCQ	30-116	78.57	27.84
KCCQ Activity	10-53	33.13	15.62
KCCQ Symptom	10-60	34.95	13.93
SF-36	56-90	67.73	9.67
SF-36 Activity	10-29	18.0	7.28
SF-36 Pain/Distress	13-40	23.71	6.84
BDI-II	0-37	11.79	9.00
NIS	15-60	57.35	33.03

Table 7

Correlation Matrix for Depressive Symptoms, Self-reported Neurological Impairment, and Quality of Life (N = 23)

	BDITOT	NISTOT	KCCQSUM	SF36SUM
BDITOT		.79**	-.65*	-.01
NISTOT			-.51	-.07
KCCQSUM				.13
SF36SUM				

* $\underline{p} < .05$, two tailed

** $\underline{p} < .01$, two tailed

Table 8

Correlation Matrix for Depressive Symptoms, Self-reported Neurological Impairment, and Quality of Life Subscales (N=23)

	BDITOT	NISTOT	KCCQA	KCCQP	SF-36A	SF-36P
BDITOT		.79**	-.51	-.69**	-.38	.50*
NISTOT			-.40	-.54**	-.29	.53*
KCCQ Activity				.81**	.54*	-.36
KCCQ Pain					.55*	-.36
SF-36 Activity						-.42
SF-36 Pain						

* $\underline{p} < .05$, two tailed

** $\underline{p} < .01$, two tailed